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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,583	07/11/2002	Joyce S. Plested	11560-003US1	2536

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EXAMINER

DEVI, SARVAMANGALA J N

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 09/08/2003

7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/089,583

Applicant(s)

Plested et al.

Examiner

S. Devi, Ph.D.

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE one MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Sep 13, 2002
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-41 ~~is~~/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-41 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: EP 0 941 738 A1

Lack of Unity of Invention(s)

- 1) Claims 4, 5, 9-14, 17, 19-22, 24-27, 35-37 and 41 have been amended.
Claims 1-41 are under prosecution.
- 2) **Please Note:** In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your election responses. The Fax number is 703-308-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Paula Hutzell, Ph.D., Supervisory Patent Examiner at Paula.Hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.
- 3) The instant inventions lack unity under PCT Rule 13.1 and 13.2:
 - I. Claim 14, drawn to a neisserial inner core reactive with the B5 antibody eliciting functional antibodies against strains within the pathogenic neisserial species.
 - II. Claim 19, drawn to a neisserial inner core reactive with the A4 antibody eliciting functional antibodies against strains within the pathogenic neisserial species.
 - III. Claims 31 and 33, drawn to the B5 antibody and hybridoma producing the same.
 - IV. Claims 32 and 34, drawn to the A4 antibody and hybridoma producing the same.
 - V. Claim 36, drawn to a method for the treatment of *Neisseria* infection by administering an antibody to neisserial inner core.
 - VI. Claim 37, drawn to a method for the treatment of *Neisseria* infection by administering a neisserial inner core-based vaccine.
 - VII. Claim 38, drawn to a method for the identification of immunogenic neisserial epitopes by generating antibodies to the inner core.
 - VIII. Claim 39, drawn to the use of biosynthetic pathway genes in the production of a neisserial strain.
 - IX. Claim 40, drawn to the use of an immunogenic neisserial inner core in the preparation of a medicament.
 - X. Claim 41, drawn to the use of an antibody in the preparation of a medicament.

Claims 1-13, 15-18 and 21-28 are considered as linking claims and would be joined with one of inventions I and II, if elected.

4) Inventions I-X lack unity of invention due to the absence of a special technical feature. The special technical feature in the instant application, as claimed for example in claim 1, is a generic vaccine comprising a neisserial inner core-based immunogenic component capable of eliciting functional antibodies against strains of a pathogenic neisserial species. However, such a vaccine was already known in the art. For instance, Arumugham *et al.* (EP 0941738) taught such a vaccine. See abstract; claims; Table 3; and sections [0062] and [0063]. Inventions VI and IX are drawn to first and second methods of using the vaccine. Although the first claimed product of the invention and the first method of using or making the product is a permitted combination under PCT Rule 13.2, in the instant case, since the special technical feature is already disclosed in the art, the special technical feature is not a unifying feature. Inventions III and IV are drawn to second and third claimed antibodies generated by two different hybridoma cell lines, and inventions V and X are drawn to different methods of using the antibody. Inventions VII and VIII are drawn to methods that do not use the products of inventions I through IV. In the instant application, since the special technical feature is already taught by the prior art, it does not define over the prior art. Therefore, technically, the absence of a special technical feature would permit the separation of the method of using or making the product from the product itself.

5) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (703) 308-9347. A telephone message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

August, 2003


S. DEVI, PH.D.
PRIMARY EXAMINER